

## SPECIALISTS IN REPRODUCTIVE MEDICINE & SURGERY, P.A.

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12/29/99

Dockets Management Branch (HFA-305)  
Food & Drug Administration  
5360 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: Docket #97N-484S  
Suitability Determination for Donors of Human Cellular and Tissue-Based Products.

To whom this may concern:

Regulation should improve the quality of life for our fellow patients, not impair it. In review of the proposed rules and regulations (bottom of page <http://www.fda.gov/cber/tissue/docs.htm>) with respect to the field of the Assisted Reproductive Technologies (ART), a number of consequences must be detailed should the proposals be accepted:

1. There is absolutely no data that oocytes, embryos or isolated sperm cells used with In Vitro Fertilization (IVF) have ever been shown to transfer sexually transmitted diseases (STD's). We are dealing with the transfer of a minimum of tissue and cells in patients already screened for STD's.
2. If you require that embryos from egg donation or gestational surrogacy be cryopreserved before transfer, you will sentence my patients to a tripling of the costs of procedures per delivered child. As an example, the cost per delivery with a fresh transfer for egg donation is estimated at about \$26,000 in my practice (48% take-home-baby rate per embryo transfer). The costs for performing only frozen embryo transfers (FET) would include the retrieval and FET transfer fees (total near \$16,000) with an estimated cost per delivery at \$53,000 (30% take-home-baby-rate for a FET's). Similar price increases would be seen in the cases of gestational surrogacy. Certainly, this decision sentence my patients to such an increase in fees should be based on science and not conjecture.
3. By forcing the egg donation recipients and gestational surrogacy commissioning couples to have the embryos quarantined by cryopreservation prior to transfer, we will lose approximately one-third of the embryos. Life is far too precious to require the unnecessary destruction of any embryos.
4. Delaying the process will result in older patients going through labor and delivery -- at least six months older than if the transfer had been done with the fresh embryos. It is well

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understood that pregnancy complications increase as the maternal age increases. The very concept of protecting the patient through these proposed regulations may result in greater physical harm to these same patients, not even taking into account the emotional distress of delaying the embryo transfer.

In the eyes of ART, semen, isolated sperm cells, eggs and embryos are not the same. When donor sperm is used, millions of cells and a much larger volume of fluid is transferred. The concern for the transmission of STD's is real in this particular instance. That clearly stated, isolated sperm cells, eggs and embryos are fundamentally different with these entities consisting of a minimum amount of tissue and fluid.

Certainly, a compromise is in order. I propose that the six-month quarantine not be mandatory, but instead, be purely optional. The FDA could assist in drafting language that could be included in the egg donation and gestational surrogacy consent forms explaining the theoretical issues at hand. By doing so, we would place the decisions squarely on the shoulders of the patients, the very patients the proposed regulations are poised to protect. I suspect there will be a rare patient, when presented with the facts as we currently understand them, who will want the fresh embryos cryopreserved. I am not simply offering criticism with this letter, but rather, a viable alternative.

Understanding that the motivation to establish rules and regulations is to improve patient care and to protect the recipient of donated materials, the proposed guidelines are entirely out of proportion to the known risks. I implore you to reconsider the proposed regulations from the perspective of known science and not fear or conjecture.

Sincerely,



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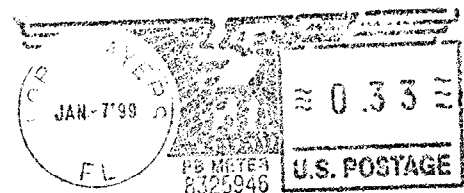
Updated

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